EXHIBIT B

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**MDL No. 2327**
	2:12-md-02327
THIS DOCUMENT RELATES TO:	**HON. JOSEPH R. GOODWIN**
Dawn Baker, et al. v. Ethicon, Inc.., et al No. 2:12-cv-02476	

RULE 26 EXPERT REPORT OF KONSTANTIN WALMSLEY, MD

My name is Konstantin Walmsley. I have been retained by the Motley Rice Law Firm to give medical opinions related to Dawn Baker. I am being compensated at the rate of $500 dollars/hour. My curriculum vitae and schedule of previous testimony are attached to this report. All opinions set forth in this report are based upon my personal knowledge, as well as my review of the pertinent medical records, my education, training, skill, experience as a physician, and review of the pertinent medical literature. All of my opinions are based upon a reasonable degree of medical probability.

I am a licensed physician in the State of New Jersey and a board certified urologist. I am familiar with the evaluation and treatment of stress urinary incontinence. I have implanted transvaginal mesh and am familiar with the properties of these devices and proper implantation technique for these devices.

I am familiar with the evaluation and treatment of stress urinary incontinence. I have implanted transvaginal mesh, including mid urethral slings, and am familiar with the properties of these devices and proper implantation technique for these

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devices. Further, I am familiar with non-mesh options for the treatment of stress urinary incontinence including the pubovaginal sling. I have attending training provided by Ethicon, Inc. regarding the TVT device. I have explanted and performed other revision procedures on transobturator and retropubic mid-urethral slings including the TVT device.

Additionally, in light of my training, knowledge, experience and qualifications as set forth above and in the attached C.V., I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by pelvic repair mesh implants.

The most common complications are pelvic pain, scarring in the vagina and pelvic floor, pain into the legs and thighs, dyspareunia, chronic inflammation of tissue, scar bands or scar plates in the vagina, vaginal shortening or stenosis, erosion, exposure or protrusion of mesh into and through tissues or organs, voiding dysfunction relating to pelvic floor scarring (de novo urinary urgency, urge incontinence, and incomplete emptying), and nerve entrapment. In diagnosing and treating patients with mesh related complications, I often determine the cause of the patients complications based upon an interview with the patient, a review of her medical records, and knowledge of her prior medical history.

I have reviewed the following medical records and depositions with accompanying exhibits pertaining to Dawn Baker:

- Baptist Health Paducah Hospital;
- Saint Thomas Midtown Hospital;
- LabCorp of America;
- Massac Memorial Hospital;
- Paducah Womens Clinic;
- Rural Health, Inc.;
- Prairie Cardiovascular Consultants Limited;
- Jeffrey Lange, D.C.;
- Pamela Hodges, M.D.;
- Western Baptist Hospital;
- Deposition – Dawn Baker.

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In addition to the review of the medical records listed above, I performed an independent medical examination of Dawn Baker on June 20th, 2016. I have also reviewed medical literature and other TVM related documents and have relied, in part, on the documents enclosed in my reliance list provided as **Appendix A**.

Clinical History

- On August 11th, 2004, Mrs. Baker underwent colposcopy revealing cervical intraepithelial neoplasia (CIN III). Her past surgical history was in part remarkable for vaginal hysterectomy in 2002, tubal ligation, and urethral dilation.

- On September 1st, Dr. Alison Strnad performed a Loop Electrosurgical Excision Procedure (LEEP) and Endocervical Curettage (ECC) procedure revealing CIN III.

- On May 14th, 2009, Mrs. Baker saw Dr. Pamela Hodges with complaints of stress urinary incontinence (SUI), nocturia and over active bladder. The patient had seen Dr. Kupper and was told that she had excessive vaginal tissue and an overactive bladder. She was prescribed Detrol LA and recommended to have urodynamics.

- On June 5th, 2009, she returned to Dr. Hodges' office, noting no improvement with the Detrol LA.

- On June 17th, she underwent urodynamics confirming the presence of SUI. Her Detrol was discontinued and she was advised to undergo placement of a TVT-Secur sling.

- On June 18th, 2009, Mrs. Baker underwent implantation of a TVT-Secur sling by Dr. Pam Hodges. The procedure occurred uneventfully. Estimated blood loss was 50 cc.

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- On June 30th, 2009, Mrs. Baker saw Dr. Hodges in follow-up. Mrs. Baker noted a few accidents the week prior, and less nocturia than before surgery. She denied any pain, bulge or discharge.

Methodology

My general opinions are based upon my clinical experience and review of medical and scientific literature and well as my medical education, knowledge, training, practice, and clinical experience.

My case specific opinions are based upon a differential diagnosis methodology. In determining the specific cause of an injury in the medical context it is necessary to "rule in" potential causes of the injury, and then by process of elimination, to "rule out" the least likely causes to arrive at the most likely cause.

General Opinion No. 1

Facilitating informed consent is an integral part of the practice of medicine. I agree with AMA 8.08 on informed consent. The patient's right of self-decision is particularly important when surgical intervention regarding a permanent medical device is being considered by the patient.

Before a surgeon can inform a patient on the risks/benefits/alternatives to any procedure, including the TVT, the surgeon must be informed on the risks/benefits/alternatives. I have read and relied on Instructions for Use (IFU) for medical devices when informing myself on the risks/benefits/alternatives to a given procedures – including mid-urethral slings. I incorporate the risks and complications referenced in the IFU into my risk benefit conversation with the patient. I expect the risk and complication information as presented in the IFU to be accurate.

It is my opinion the IFU for the TVT-Secur in 2009 were not sufficient to enable informed consent from the patient. The TVT-Secur IFU provided:

ADVERSE REACTIONS

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- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE mesh is designed to minimize the risk of contamination.
- Over correction i.e. too much tension applied to the tape may cause temporary or permanent lower urinary tract obstruction.

ACTIONS

Animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

The words "transitory" and "transient" carry a specific medical meaning. Mosby's medical dictionary defines transient as "pertaining to a condition that is temporary." Using the word transient to describe the human body's foreign body response to the TVT mesh implies the response dissipates with time. In my experience, this does not accurately describe the human body's foreign body response to transvaginal placed mesh.

In my experience when dealing with synthetic mesh-induced foreign body response, the degree of inflammation and scarring around the mesh is intense and chronic. More often than not, when removing exposed mesh, I am unable to completely remove the entire mesh implant because of the intensity of inflammation and extensive scarring induced by mesh incorporation into the host tissues. Moreover, in all of my experiences removing mesh, residual scarring of the vagina and peri-vaginal tissues persists and is even more severe in the instances where residual pelvic mesh is left in the patient.

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The TVT-Secur IFU does not mention: mesh contraction; dyspareunia; mesh shrinkage; scar plate formation; or the difficulty in removing mesh in the event of an adverse event. These events are all part of my informed consent conversation today. I have treated patients implanted with mid-urethral slings, including the TVT for these conditions. These events were reported in the mid-urethral sling literature prior to when Mrs. Baker was implanted. In my opinion, a patient considering a mid-urethral sling cannot be properly consented without discussing these potential adverse events.

General Opinion No. 2

Safer alternatives designs and procedures existed in 2009 that have a lesser risk of erosion and dyspareunia with substantially equivalent efficacy.

In 2009, alternative successful and safer sling procedures were available, including autologous fascial slings using rectus fascia sutured to the bladder neck and tied to itself over the rectus fascia. Mrs. Baker was unable to receive proper informed consent relating to this safer alternative because of the lack of information in the TVT-Secur IFU inherent to the risks of using synthetic mesh. As such, Dr. Hodges was unable to warn Mrs. Baker of the subsequent complications she has suffered from.

Case Specific Opinion No. 1

Mrs. Baker suffered scar plate formation as a result of the physical properties of the TVT-Secur device. These conditions are documented in my independent medical evaluation (IME) of Mrs. Baker.

During my physical examination Mrs. Baker, I identified vaginal scarring and induration along her anterior vaginal wall in the area of vaginal sulci, more so on the right side than the left side.

I have observed scar plate formation in patients such as Mrs. Baker who have had TVT-Secur slings implanted.

Case Specific Opinion No. 2

Mrs. Baker's pelvic pain and dyspareunia was caused by scar plate formation around the TVT-Secur device. Recognized causes of dyspareunia following synthetic

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sling surgery include: (1) erosion/extrusion; (2) mesh contraction; (3) paraurethral banding; (4) scarring with reduced elasticity; (5) infection and inflammation including but not limited to vestibulitis; (6) neuromuscular injury (7) lichen sclerosis; (8) vaginal tissue atrophy; and (9) pelvic floor dysfunction.

I am able to rule out erosion as a cause of Mrs. Baker's dyspareunia in 2009. There is no evidence of this in the medical records I've reviewed nor in my pelvic examination performed during my IME.

I am able to rule in scarring with reduced elasticity as a cause of Mrs. Baker's vaginal pain and dyspareunia. I identified this finding during my physical examination of Mrs. Baker. Specifically, induration noted along the vaginal sulci underneath the sling as well as pain produced on palpation in this area enables me to rule in contraction and scarring as a potential cause of Mrs. Baker's dyspareunia.

I am able to exclude paraurethral banding as a cause of Mrs. Baker's dyspareunia and vaginal pain because I have seen no paraurethral banding documented.

I am able to exclude vestibulitis, and lichen sclerosis as causes of Mrs. Baker's vaginal pain and dyspareunia.

Vaginal tissue atrophy is excludable as the cause of Mrs. Baker's dyspareunia as she never was diagnosed with this condition and is pre-menopausal as well, making the likelihood of this condition practically impossible.

I am also able to exclude pelvic floor dysfunction as the cause of Mrs. Baker's dyspareunia. The absence of documented tenderness to the pelvic floor musculature by multiple consultants during multiple examinations enables me to reasonably exclude pelvic floor dysfunction as a potential cause of Mrs. Baker's dyspareunia.

Case Specific Opinion No. 3

Mrs. Baker continues to have dyspareunia and pelvic pain presently. As part of my expert review and preparation of my opinion regarding Mrs. Baker, I performed an independent medical exam of this patient on June 20th, 2016. At that time, the patient reported several bothersome symptoms including voiding dysfunction, pelvic pain and dyspareunia. Her voiding dysfunction consisted of mixed urinary incontinence, primarily urgency-related. She also complained of an intermittent pulling, painful sensation in her right groin. She described having been sexually active two to four times per week but now not being able to have

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intercourse at all because of the pain. She further characterized this pain as being located just beyond the vaginal introitus on the right side.

On physical exam, there was notable tenderness upon palpation along the vaginal sulci, right greater than left where there was induration consistent with scar and fibrosed vaginal tissue. As part of the foreign body reaction to synthetic mesh the periurethral, perivesical, and vaginal tissues create dense fibrotic scar tissue which compromises the elasticity and compliance of these tissues. As such, when patients present with voiding dysfunction following synthetic mesh sling implantation, it tends to manifest itself as both obstructive in nature in combination with mixed urinary incontinence (MUI). This relates to a combination of factors, one being the development of non-compliant "pipestem" urethral tissues that are unable to coapt and therefore hold urine; the second factor relates to a combination of (1) inflammation rendering the bladder muscle (or detrusor muscle) unstable, as well as (2) scarring of the bladder muscle adjacent to the synthetic mesh foreign body response, in which the bladder muscle's ability to contract is compromised because of scarring and fibrosis. Mrs. Baker currently has this complaint having evolved from a patient with an SUI- dominant incontinence picture to a predominantly urgency urinary incontinence (UUI) form of MUI.

Case Specific Opinion No. 4

Mrs. Baker's future prognosis as it relates to her vaginal pain, dyspareunia, and voiding dysfunction is guarded. Because she has pelvic mesh still inside of her body, she will continue to suffer from vaginal pain and dyspareunia. Moreover, she has pelvic tenderness and residual scar tissue in the area where her mesh erosion was treated. Even if she were to have all of her mesh removed, the surgery require to execute this procedure is challenging, complicated, and likely to create further vaginal scarring. I anticipate that if heroic surgery were performed to remove all of her mesh that she would develop further scarring and fibrosis inherent to this procedure. Although these interventions could be somewhat helpful, they most certainly will not resolve the voiding dysfunction she currently suffers from.

With regards to her dyspareunia, her symptoms might be partially ameliorated with sling removal. Once again, this would be a heroic procedure likely performed in a tertiary academic center and would likely create further fibrosis and scarring which would more likely than not result in persistent dyspareunia. In

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summary, within a reasonable degree of medical certainty, the voiding dysfunction, vaginal pain, and dyspareunia will be a lifelong condition for this patient.

I reserve the right to supplement and amend this opinion should additional factual information be forwarded to me that I did not have available at the time this opinion is submitted.

Dated this the 8th day of July, 2016

Sincerely,

Konstantin Walmsley, M.D.